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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,936	09/25/2003	Hanna Cotton	1103326-0502 CON.	9504

7470 7590 11/21/2005  
WHITE & CASE LLP  
PATENT DEPARTMENT  
1155 AVENUE OF THE AMERICAS  
NEW YORK, NY 10036

EXAMINER

AULAKH, CHARANJIT

ART UNIT PAPER NUMBER

1625

DATE MAILED: 11/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/672,936

Applicant(s)

COTTON ET AL.

Examiner:

Charanjit S. Aulakh

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2, 14, 17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 14, 17 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. According to paper filed on Oct. 28, 2005, the applicants have filed a RCE and furthermore, have amended claim 18.
2. Claims 1, 2, 14, 17 and 18 are now pending in the application.

### ***Response to Arguments***

3. Applicant's arguments filed on Oct. 28, 2005 have been fully considered but they are not persuasive regarding obviousness and double patenting rejections. The applicants have amended claim 18 to overcome indefiniteness rejections. In regard to obviousness rejections, the examiner does not agree with the applicants arguments since the utility is identical. The applicants did not provide any unexpected data of superior activity, physical and chemical properties of instant trihydrate of S-omprazole magnesium salt as compared to dihydrate of S-omprazole magnesium salt of the two cited references. Also, what is the evidence that the trihydrate or crystalline form is maintained in the pharmaceutical composition or following in vivo administration of magnesium salt of S-omprazole? The applicants did not address this issue at all in their response. In regard to double patenting rejection, the examiner does not agree with the applicants arguments that the instant claims and those of the cited patent are related as genus and species. The instant claims as well as claims of the cited patent are directed to magnesium salt of S-omprazole trihydrate and therefore are identical. The applicants did not provide any reasons or evidence to show how the scope is different?

**Conclusion**

4. Rejections under 35 U.S.C. 103(a) and 35 U.S.C. 101 are maintained for the reasons of record.

**NEW GROUNDS OF REJECTION**

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 17, the term ---one or more therapeutically active ingredients --- is indefinite since specific active ingredients which are enabled by the instant specification are not defined.

In claim 18, the term ----inhibiting gastric acid secretion --- is indefinite since the degree of inhibition ( 20%, 40%, 60%, 80% or 100% ) is not defined and furthermore, how this inhibition is being assessed in vivo following administration of instant compounds? What is the end result of this inhibition? What is being treated? The applicants are suggested to amend claim to read as --- A method of treating ulcer -----.

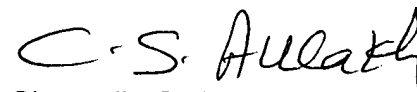
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is

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(571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charanjit S. Aulakh  
Primary Examiner  
Art Unit 1625